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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,834	02/02/2004	Nikolai M. Krivitski	86017.000038	9076

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EXAMINER

WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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08/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/769,834	Applicant(s) KRIVITSKI ET AL.	
	Examiner Eric F. Winakur	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/7/04; 8/14/08</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claims 1 - 11 are objected to because of the following informalities: With regard to claim 1, it appears that the phrase "blood passing" (line 8) should refer to "diluted blood passing" and that the limitation of step (d) should set forth that the determining a calibration coefficient of the blood property sensor is "based on the determined property" to properly refer to the result of the previous step. With regard to claim 8, it appears that the phrase "the blood" (line 8) should refer to "the diluted blood". With regard to claim 9, it is somewhat unclear as written; the claim has been interpreted to mean "wherein introducing the indicator bolus is effective to change an ultrasound velocity in the blood" and Applicant is requested to amend the claim with similar language, if such an interpretation was correct or to make other amendments, if necessary, to clarify the claim's meaning. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how performing the step of changing an ultrafiltration rate could introduce a substance into the system; further, the relationship between the step of claim 3 and step (b) of claim 1 is unclear.

Claim Rejections - 35 USC § 102

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 8 - 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Krivitski. Krivitski teaches a measurement arrangement (Figure 11; column 8, line 49 - column 9, line 3) suitable for measuring from tubing of a hemodialysis arrangement and gives details of various sensors (Figures 12 - 15; column 9, lines 31 - 61) that may be used in such an arrangement. Krivitski further teaches details related to calibration of the sensing arrangement (column 11, lines 10 - 36).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 - 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krivitski. Krivitski, as detailed above, teach details of a measurement arrangement and calibration thereof. When describing the calibration, Krivitski give an example of calibration by injection in arterial inlet ports (column 11, lines 15 - 36) and also teach that similar sensors are located on the venous portion of the arrangement of Figure 11, but do not particularly teach that the sensors on the venous portion are calibrated in the same manner. However, without a showing of unexpected results or criticality, it would

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have been within the skill level of the art to implement the calibration routine on the venous side sensors to permit calibrated measurements to be obtained therefrom as well, since there is a reasonable expectation that the disclosed calibration technique would be suitable for calibrating the sensors regardless of whether they were on arterial or venous side tubing and one would recognize the importance of performing measurements with calibration of all of the sensors.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571/272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768